JUL 12 2011

K110538 1/2

510(K) SUMMARY

1 Submitter Information

A.	Company Name:	Synovis Orthopedic and Woundcare, Inc.
B.	Company Address:	6 Jenner, Suite 150 Irvine, CA 92618
C.	Company Phone:	(949) 502-3240
D.	Company Facsimile:	(949) 502-3241
E.	Contact Person:	Amy Boucly Manager, Regulatory Affairs

2 Device Identification

A.	Device Trade Name:	PRO Fixation™ System
B.	Common Name:	Suture Anchor
C.	Classification Name(s):	Screw, Fixation, Bone
D.	Classification Regulation:	888.3040
E.	Device Class:	Class II
F.	Device Code(s):	HWC, MBI
G.	Advisory Panel:	Orthopedic

3 Identification of Predicate Devices

The PRO Fixation™ System is substantially equivalent to the following devices, which are cleared for commercial distribution in the United States:

- PushLock™, Arthrex, Inc., K051219
- Arthrex Tenodesis Family, Arthrex, Inc, K051726
- Corkscrew FT, Arthrex, Inc., K050358, K061665
- FOOTPRINT Ultra PK Suture Anchor, Smith & Nephew, Inc., Endoscopy Division, K073509/ K093897

4 Device Description

The PRO Fixation™ System is a sterile single use device intended for the reattachment of soft tissue to bone. The PRO Fixation System is comprised of an implantable non-absorbable anchor and a disposable inserter. The anchor allows for placement, suture tensioning, and fixation of soft tissue into bone. Anchors will be available in a range of sizes.

5 Statement of Intended Use

Intended for the reattachment of soft tissue to bone in the shoulder, foot/ankle, knee, elbow and hand/wrist for the following indications:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-Foot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon Reconstruction, Tendon Transfer in the Foot and Ankle

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpal Ligament Reconstruction and Repair, Tendon Transfer in the Hand/Wrist

6 Non-Clinical Testing

Testing has been conducted to evaluate the biological safety and performance characteristics of PRO Fixation™ System.

Biocompatibility results indicate that the device biocompatibility profile is equivalent to the predicate devices.

Laboratory testing was performed to verify that pull-out strength, suture integrity/tensile strength following anchor insertion, suture slip resistance, and anchor and driver integrity meet mechanical performance requirements for the product's intended use and are comparable to predicate devices.

7 Comparison with Predicate Devices

The PRO Fixation™ System is comparable to the predicate devices in terms of intended use, technology, design, materials and biocompatibility and performance: It is similar to the predicate devices in that it has the same intended use of soft tissue to bone reattachment, is comprised of similar materials and is similar in design. All test results demonstrated that the performance of PRO Fixation™ System is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Synovis Orthopedic and Woundcare, Inc.
% Ms. Amy Boucly
6 Jenner Street
Suite 150
Irvine, CA 92618

JUL 12 2011

Re: K110538
Trade/Device Name: PRO Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, MBI
Dated: June 17, 2011
Received: June 20, 2011

Dear Ms. Boucly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K110538

Device Name: PRO Fixation™ System

Indications for Use:

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Prescription Use ___X___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110538